

Notice of Allowability

Application No.

10/629,348

Applicant(s)

HELLER ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/08/2007.
2. ☒ The allowed claim(s) is/are 45-109.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Allowable Subject Matter

1. Claims 45-109 are allowed.
2. The following is an examiner's statement of reasons for allowance: each of the independent claims (claims 45, 67, and 70) requires the integrated unit to be disconnectable from the analyzer as the integrated unit.

In Nakashima as modified by Asa and Bratten the sensor (4) is held by the cap (2), which is mechanically attached to the analyzer (1). See Figure 2 in Nakashima. Although the cap (and thus the sensor) and the piercing member (3) are disconnectable from the analyzer (see page 2 of Nakashima¹) and the sensor and the piercing member are mechanically attached together to form an integrated unit when the analyzer is completely assembled (Figure 1), the cap (and thus the sensor) must be removed first and separately before the piercing member can be removed. This is inferred from Figures 2 and 3 and the first three paragraphs on page 6 of Nakashima.

¹ "... a lancet mounted in an appropriate position of the main body of the measurement device in a quick connect/disconnect manner, a cap body for the lancet to fit on the aforementioned main body of the measurement device in a quick connect/disconnect manner and covering the lancet ..."

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In Diebold as modified by Schindele, Miyawaki, and Straus a stopper (350 - Schindele) is fitted over the sensor (301) or the sensor must have a flow path through the entire length of the sensor (element 13 in Figure 3 and elements 15 and 16 in Figure 4 of Miyawaki). However, the sensor in Diebold is a flat strip sensor having a capillary channel (49) that extends only a part of the length of the sensor from its front end. See Figures 3-6 in Diebold. The Diebold sensor cannot readily or with little modification be fitted on the stopper of Schindele or replace the cylindrical sensor cartridge (301) of Schindele. Also, the channel in the Diebold sensor is designed to draw sample by capillarity and has vent ports on the top and bottom of the sensor, so it is also not readily compatible with the configuration of Miyawaki in which the sample is drawn through the sensor by vacuum from a plunger behind the sensor.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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AU 1795
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